

43rd Annual NCDEU Meeting PROGRAM

May 27-30, 2003 Boca Raton, Florida

Monday, May 26, 2003

New Investigator's Workshop (Closed)

8:30 am- 5:30 pm

Tuesday, May 27, 2003

WORKSHOP 1

9:00 AM - 12:00 Noon

Complementary and Alternative Treatments: Research Challenges

Chairs: Andrew A. Nierenberg, M.D., (Harvard Medical School)

Nancy J. Pearson, Ph.D., (National Center for Complementary and

Alternative Medicine)

Introduction

NCCAM: Overcoming Challenges to Clinical Trials with Natural Products,

Margaret A. Chesney, Ph.D., (National Center for Complementary and Alternative Medicine)

Basic Mechanisms: Nuclear Xenobiotic Receptor PXR: A Molecular Target for St. John's Wort

Steven A. Kliewer, Ph.D., (University of Texas - Southwestern Medical Center)

Break

Adventures with the Herbal Industry: Vetting the Source for St. John's Wort

Andrew A. Nierenberg, M.D., (Harvard Medical School)

Fishing for Efficacy: the Omega-3 Story

David Mischoulon, M.D., Ph.D., (Harvard Medical School)

The Ginkgo in Evaluation of Memory (GEM) Dementia Prevention Trial: Challenges and

Opportunities

Steven T. DeKosky, M.D., University of Pittsburgh

General discussion and conclusions

Tuesday, May 27, 2003

WORKSHOP 2

Enhancing Precision in Clinical Trials VI

Part 1: 9:00 AM - 12:00 Noon Part 2: 1:00 PM - 5:00 PM

Chair: Mark Rapaport, M.D., Cedars-Sinai Hospital

Morning Session (9 a.m. – 12 p.m.) Applications

9:00 – 9:05 a.m.	Introduction and Opening Remarks on Applications Mark Rapaport (Cedars-Sinai Hospital)	
9:05 – 9:40 a.m.	Patient-based quality of life and health outcomes assessment John Ware (QualityMetric)	
9:40 – 10:15 a.m.	IVR diary methods to reduce retrospective recall bias in sleep studies Berrnice Kuca (Sepracor)	
10:15 – 10:30 a.m.	Break	
10:30 – 11:05 a.m.	Traditional vs. Enriched Rater Training for a Multi-Site Depression Trial: A pilot study of effectiveness and feasibility Nina Engelhardt (Eli Lilly)	
11:05 – 11:40 a.m.	Assessing Patients in Psychiatric Drug Trials: A Regulatory Perspective: Tom Laughren (FDA)	
11:40 – Noon	Wrap-up and Concluding Comments on Application Mark Rapaport (Cedars-Sinai Hospital)	
Afternoon Session (2 p.m. – 5 p.m.): Theory		
2:00 – 2:05 p.m.	Introduction and Opening Remarks on Theory Mark Rapaport (Cedars-Sinai Hospital)	
2:05 – 2:40 p.m.	An activity update for the NIMH Conference, Assessment of Depression and Anxiety in Depression Treatment Trials David Kupfer (Western Psychiatric)	
2:40 – 3:15 p.m.	Methodological Issues arising from the Pregabelin and Sertraline Trials in Generalized Anxiety Disorder Catherine Clary (Pfizer)	
3:15 – 3:30 p.m.	Break	
3:30 – 4:05 p.m.	New self-report assessments and methodological issues in clinical trials David DeBrota (Eli Lilly)	
4:05 – 4:40 p.m.	Update on study methodology and self-report in a very large NIMH trial: A. John Rush (University of Texas Southwestern)	
4:40 – 5:00 p.m.	Wrap-up and Concluding Comments on Theory, Mark Rapaport (Cedars-Sinai Hospital)	

Tuesday, May 27, 2003

WORKSHOP 3

Beyond Short-Term Treatment Effects: Can We Change the Course of Illness Through Treatment?

Part 1: 9:00 AM - 12:00 Noon Part 2: 1:00 PM - 5:00 PM

Morning Session (9 a.m. – 12 p.m.) Studying Possible Long-Term Effects of Interventions

Chair: Benedetto Vitiello, M.D., NIMH

9:00 am – 9:10 am	Introduction
9:10 am – 9:50 am	Extended follow-up in the multimodal treatment study of children with ADHD (MTA) L. Eugene Arnold, M.D. (Ohio State University)
9:50 am – 10:30 am	The effect of stimulant medication on outcomes of adolescents and young adults with ADHD William Pelham, (State University of New York at Buffalo)
10:30 am – 10:40 am	Break
10:40 am – 11:20 am	Are there persistent effects of cognitive-behavioral therapy in depressed adolescents? Gregory Clark, Ph.D., (Kaiser Research Foundation)
11:20 am – 12:00 noon	Detecting distal effects on low base-rate disorders: what can we learn from prevention research? Hendricks Brown, Ph.D., (University of South Florida)

12:00 noon Lunch break

 $\begin{tabular}{ll} Afternoon Session (1:00 p.m.-5:00 p.m.): & {\bf Studying the \ Long-Term \ Safety of Pharmacological \ Treatment in \ Children} \end{tabular}$

Chair: Laurence L. Greenhill, M.D., (Columbia University)

1:30 pm – 2:10 pm	Is there a European regulatory perspective to studying long-term pharmacological effects in naturalistic settings? Joerg Fegert, M.D., (University of Ulm)
2:10 pm – 2:50 pm	Stimulant medications and growth in children with ADHD James Swanson, Ph.D., (University of California at Irvine)
2:50 pm – 3:20 pm	Stimulant medications and risk of substance abuse Lily Hechtman, M.D., (McGill University)
3:20 pm – 3:30 pm	Break

3:30 pm – 4:10 pm	Childhood methylphenidate and substance involvement 30 years later: methodological considerations Jan Loney, Ph.D., (University of Iowa)
4:10 pm – 4:50 pm	Long-term treatment of children with autism with risperidone. Michael Aman, Ph.D., (Ohio State University)
4:50 pm – 5:00 pm	General discussion and conclusions

Tuesday, May 27, 2003

WORKSHOP 4

Subject Diversity in Clinical Trials: Is Recruitment Enough?

2:00 PM - 5:00 PM

Chairs: William B. Lawson MD, PhD, (Howard University)

Sherman L. Ragland, M.S.W., (National Institute of Mental Health)

Dorothy on the Yellow Brick Road: Innovation, Infrastructure and Diversity in Clinical Trials

Keh Min Lin, M.D., MPH, (Harbor-UCLA Research and Education Institute)

Tanya N. Alim, M.D., (Howard University)

Special Issues for the Recruitment, Retention, and Assessment of Older People with Psychotic Disorders in Clinical Trials

Jonathan P. Lacro, Pharm.D., (VA San Diego Healthcare System and University of California, San Diego)

Subject Diversity in Clinical Trials: From schizophrenia to Refugee Populations David C. Henderson, M.D., (Massachusetts General Hospital)

TREATMENT DEVELOPMENT SESSION 1

Pharmacogenetics of Mood and Anxiety Disorders

9:00 AM - 11:00 AM

Chair: Francis McMahon, M.D., (National Institute of Mental Health)

9:00 am-9:30 am	Tackling the genetics of pharmacogenomics Francis J McMahon, MD, (National Institute of Mental Health)
9:30 am-10:00 am	Recent Advances and Clinical Applications of Pharmacogenetics in Psychiatry TBA
10:00 am-10:30 am	Pharmacogenetics of mood stabilization in bipolar disorder Martin Alda, MD, FCRPC. (Dalhousie University, Halifax, Canada)

10:30 am-11:00 am Panel Discussion

Tuesday, May 27, 2003

TREATMENT DEVELOPMENT SESSION 2

New Approaches in Drug Discovery

1:00 PM - 3:00 PM

Chair: Linda S. Brady, Ph.D., (National Institute of Mental Health)

1:00 pm – 1:30pm	Screening the Receptorome Reveals Unexpected Targets for Drug Discovery Bryan Roth, Ph.D., (Case Western Reserve University)
1:30 pm – 2:00pm	PET Studies of CNS NK1 Receptors with [18F]SPA-RQ in the Clinical Development of Substance P Antagonists Richard Hargreaves, Ph.D. (Merck)
2:00 pm – 2:30pm	Psychiatric Genomics: Gene-Based Target Identification for Schizophrenia, Depression, and Bipolar Disease C Anthony Altar, Ph.D., (Psychiatric Genomics, Inc.)
2:30 pm – 3:00pm	A Novel Class of Nucleic Acid Drugs Errol DeSouza, Ph.D., (Archemex Corp.)

TREATMENT DEVELOPMENT SESSION 3

MATRICS: Treatment Development for Cognition in Schizophrenia $3\!:\!30~PM$ - $5\!:\!00~PM$

Chair: Stephen R. Marder, M.D., (UCLA and VA Greater Los Angeles)

3:30 pm – 3:45pm	Treatment Development for Neurocognition in Schizophrenia Wayne S. Fenton, M.D., (National Institute of Mental Health)
3:45 pm – 4:00pm	Separable Cognitive Factors in Schizophrenia Keith Nuechterlein, Ph.D., (UCLA)
4:15pm – 4:30pm	Cognition and Functional Outcome in Schizophrenia Michael Green, Ph.D., (UCLA)
4:30 pm – 4:45pm	Pharmacological Interventions for Cognition in Schizophrenia Robert W. Buchanan, M.D., (Maryland Psychiatric Research Center)
4:45 pm – 5:00pm	NIMH/UCLA MATRICS Overview and Timeline Stephen R. Marder, M.D., (UCLA and VA Greater Los Angeles)
7:00 pm – 7:30pm 7:30 pm – 9:30 pm	New Investigators' Awards Presentation (Open) Reception (Open)

Wednesday, May 28, 2003

Welcome and News from NIMH

8:30 AM - 9:30 AM

Welcome to NCDEU Matthew V. Rudorfer, M.D.

NCDEU Program Chair

National Institute of Mental Health

Grayson S. Norquist, M.D., M.S.P.H.

Director, Division of Services and Intervention Research

National Institute of Mental Health

NIMH News and Updates Thomas R. Insel, M.D.

Director, National Institute of Mental Health

Richard K. Nakamura, Ph.D.

Deputy Director

National Institute of Mental Health

Dennis S. Charney, M.D.

Director, Mood and Anxiety Disorders Program

National Institute of Mental Health

9:30 am – 9:55 am **Break**

PLENARY SESSION: Treatment and Preventive Interventions Research: From Laboratory through Clinical Trial to Practice

10:05 AM - 12:15 PM

Chair: Wayne S. Fenton, M.D., (National Institute of Mental Health)

CNS Drug Development in the 21st Century

Edward M. Scolnick, M.D., (Merck)

Novel Targets and Approaches to Affective and Anxiety Disorders

Dennis S. Charney, M.D., (National Institute of Mental Health)

Novel Targets and Approaches to Schizophrenia

Carol A. Tamminga, M.D., (University of Maryland School of Medicine)

Science to Service

Discussant: A. John Rush, M.D., (University of Texas Southwestern Medical Center)

PANEL 1

2:15 PM - 4:15 PM

Improving the Clinical Relevance of Maintenance Designs in Bipolar Disorder

Chair: Charles L. Bowden, M.D., (University of Texas Health Science Center, San Antonio)

2:15 pm - 2:45 pmChoosing the Right Patient Population Terrence Ketter, M.D., (Stanford University) 2:40 pm - 3:10 pmChoosing the Right Outcomes Charles L. Bowden, M.D., (University of Texas Health Science Center, San Antonio) 3:10 pm - 3:40 pmSystematic Open Studies and Randomized, Placebo Controlled Studies William H. Coryell, M.D., (University of Iowa) 3:40 pm - 4:10 pmWorking in a Complex Environment: The Multiple Challenges in Studying Psychosocial Treatments for Bipolar Disorder Ellen Frank, Ph.D., (University of Pittsburgh) 4:10 pm Bridging the Efficacy vs Effectiveness Gap Discussant: Matthew V. Rudorfer, M.D., (National Institute of Mental Health)

Wednesday, May 28, 2003

PANEL 2

2:15 PM - 3:45 PM

Integration of Neurobiologic Methods into Late-Life Clinical Trials

Chairs: Gwenn Smith, Ph.D., (Zucker Hillside Hospital, North Shore - Long Island

Jewish Health System)

William Z. Potter, M.D., Ph.D., (Eli Lilly and Company)

2:15 pm – 2:35 pm *Role of Structural neuroimaging* David C. Steffens, M.D., M.H.S., (Duke University Medical Center)

2:35 pm – 2:55 pm *Integration of neurochemical brain imaging with clinical*

*trials-neurochemical substrates of treatment response variability*Gwenn Smith, Ph.D., (Zucker Hillside Hospital, North Shore - Long

Island Jewish Health System)

2:55 pm – 3:15 pm Integration of biological measures into clinical trials in

psychotic depression

Barnett S. Meyers, M.D., (Weill Medical College of Cornell

University)

3:15 pm – 3:45 pm Future Directions in treatment development and biological markers

William Z. Potter, M.D., Ph.D., (Eli Lilly and Company)

Wednesday, May 28, 2003

PANEL 3

4:30 PM - 6:00 PM

Proof of Concept Trials in Neuropsychiatric Disorders

Chairs: Herbert Harris, (Vela Pharmaceuticals) Remy Luthringer, (Forenap Institute)

4:30pm – 4:35pm	General Introduction
	Herbert Harris, M.D., Ph.D., (Vela Pharmaceuticals)
4:35pm – 4:55pm	The Emerging Scope of Proof of Concept
	William Z. Potter, M.D., Ph.D. (Eli Lilly)
4:55pm – 5:15pm	Genomics in Proof of Concept Trials
	Maria Athanasiou, Ph.D., (Genaissance Pharmaceuticals)
5:15pm – 5:35pm	CNS Disease Modeling in Human Subjects
	Remy Luthringer, Ph.D, (Forenap Institute)
5:35pm – 6:00pm	Discussion: The Proof of Proof of Concept
	Paul Andreason, M.D., (Food and Drug Administration)
	Barry Lebowitz, Ph.D. (National Institute of Mental Health)
	Fouzia Laghrissi-Tode, M.D., (Roche)

Wednesday, May 28, 2003

UPDATES-I

4:00 PM - 6:00 PM

Chair: Susan M. Essock, Ph.D., (Mount Sinai School of Medicine)

UPDATE 1

Medical Monitoring for Individuals with Schizophrenia: Results from a Consensus Conference

Stephen R. Marder, M.D., (UCLA and VA Greater Los Angeles)

UPDATE 2

Risk Management in Clinical Trials

Madhukar Trivedi, M.D., (University of Texas – Southwestern Medical School)

UPDATE 3

Research Design Features Determining Antidepressant Clinical Trial Outcome

Arif Khan, M.D., (Northwest Clinical Research Center)

UPDATE 4

Impulse Control Disorders: Neurobiology and Treatment

Larry J. Siever, M.D., (Mount Sinai School of Medicine)

Wednesday, May 28, 2003

TREATMENT DEVELOPMENT SESSION 4

2:15 PM - 3:45 PM

Case Studies: Drug Registration for Non-DSM Indications

Chair: Roger E. Meyer, M.D. Best Practices, LTD

2:15 pm – 2:40 pm *Clozapine as a Treatment for Suicidality in Schizophrenia:*

Background, Design, and Results of INTERSEPT Study

Larry Alphs, M.D., (Novartis)

2:40 pm – 3:15 pm Can Clinical, Commercial and Regulatory Reality Converge? A

Case Study: Psychosis of Dementia

George Gharabawi, M.D., (Janssen Pharmaceutica)

3:15 pm – 3:40 pm *Challenges to Evaluating Agitation in Acute Psychosis*:

Establishing Parameters for a New Indication

Steven J. Romano, M.D., Pfizer, Inc.

3:40 pm - 3:45 pm**Discussant:** Thomas A. Laughren, M.D., (Food and Drug Administration)

Wednesday, May 28, 2003

TREATMENT DEVELOPMENT SESSION 5

4:00 PM - 6:00 PM

Innovative, Mechanism-Based Treatment Strategies in Anxiety and Depression

Chairs: Alan F. Schatzberg, M.D., (Stanford University) K. Ranga R. Krishnan, M.D., (Duke University)

4:00 pm - 4:30 pm Replication of the Efficacy and Tolerability of Substance P Antagonists in Patients with Major Depression William A. Ball, M.D., Ph.D., (Merck) 4:30 pm - 5:00 pmAcute Treatment of Bipolar Depression with an Olanzapine: Fluoxetine Combination Gary C. Tollefson, M.D., Ph.D., (Eli Lilly and Company) 5:00 pm - 5:30 pmClinical Trials of Mifepristone for Psychotic Major Depression (PMD) Joseph Belanoff, M.D., (Corcept Therapeutics, Inc.) 5:30 pm - 6:00 pmThe Role of Glutamate Antagonists in the Treatment of Anxiety K. Ranga R. Krishnan, M.D., (Duke University) 12:15 pm - 2:15 pmPoster Session I

7:00 pm - 9:00 pm**NIMH Reception (Open)**

Thursday, May 29, 2003

5th Annual Fun Run/Walk (Open) 6:30 am - 7:30 am

PANEL 4

Psychopharmacology and Reproductive Transitions

9:00 AM - 12:00 Noon

Chair: Mary C. Blehar, Ph.D., National Institute of Mental Health

9:00 am - 9:30 amSandra L. Kweder, M.D., (Food and Drug Administration)

9:30 am - 10.00 am Weight-Gain Inducing Psychotropic Medications, Gender, and

Potential Pharmacologic Strategies

Barbara L. Gracious, M.D., (University of Rochester)

10:00 am – 10:30 am	Testosterone Decline in Aging Men: Does "Andropause" Exist? Stuart N. Seidman, M.D., (Columbia University)
10:30 am – 11.00 am	Perimenopause, Mood, and Estrogens Claudio N. Soares, M.D., Ph.D., (Massachusetts General Hospital)
11:00 am – 11.30 am	Women's Health Initiative Sally Shumaker, Ph.D.
11:30 am – 12.00 pm	General Discussion

PANEL 5

9:00 AM - 10:30 AM

Cocaine Dependence Treatment: Advances in Agonist Strategies and Behavior Therapy – Pharmacotherapy Combinations

Chairs: Jack D. Blaine, M.D., (National Institute on Drug Abuse)
John Grabowski, Ph.D., (University of Texas Health Science Center, Houston)

9:00 am – 9.15 am	NIDA Medication Development Program Ahmed Elkashef, M.D., National Institute on Drug Abuse
9:15 am – 9:30 am	Effects of Continuous Infusion with Amphetamine on Cocaine Self-Administration and Food-Maintained Responding in Rhesus Monkeys S. Steven Negus, Ph.D., (McLean Hospital and Harvard Medical School)
9:30 am – 9:45 am	Biogenic Amine Releasing Agents as Agonist Substitution Therapies for Stimulant Dependence Michael H. Baumann Ph.D., (National Institute on Drug Abuse)
9:45 am – 10:00 am	Clinical Trials Large and Small of Agonists for Cocaine Dependence: Support for a Conceptual Model and Medication Development John Grabowski, Ph.D., (University of Texas Health Science Center, Houston)
10:00 am – 10:15 am	Combining Medication and Behavior Therapy for Cocaine Dependence Joy Schmitz, Ph.D., (University of Texas Health Science Center, Houston)
10:15 am – 10:30 am	General Discussion

PANEL 6

2:30 PM - 4:00 PM

Advances in Medication Adherence in Psychotic Disorders

Chairs: Dawn I. Velligan, Ph.D., (University of Texas Health Science Center, San Antonio) Nina R. Schooler, Ph.D., (Zucker Hillside Hospital, North Shore - Long Island Jewish Health System)

2:30 pm – 2:45 pm	Medication Adherence and Bipolar Disorder Gary Sachs, M.D., (Massachusetts General Hospital)
2:45 pm – 3:00 pm	Medication Adherence and Schizophrenia Peter Weiden, M.D., (SUNY Health Science Center at Brooklyn)
3:00 pm – 3:15 pm	How to Assess Medication Adherence in Psychotic Disorders Francis Lam, Pharm.D., (University of Texas Health Science Center, San Antonio)
3:15 pm – 3:30 pm	Improving Adherence to Medications Dawn I. Velligan, Ph.D., (University of Texas Health Science Center, San Antonio)
3:30 pm – 3:45 pm	Discussant: Nina R. Schooler, Ph.D., (Zucker Hillside Hospital, North Shore - Long Island Jewish Health System)
3:45 pm – 4:00 pm	General Discussion

Thursday, May 29, 2003

PANEL 7

2:30 PM - 5:30 PM

Brain Imaging Markers of Pharmacological Treatment in Children, Adolescents, and Adults

Chairs: Judith M. Rumsey, Ph.D., (National Institute of Mental Health)

Michael E. Henry, M.D., (McLean Hospital)

Clinical Studies - Chair: Judith M. Rumsey, Ph.D.

2:30 pm – 2:55 pm

**Using Neuroimaging to Assess the Effects of Antipsychotic Treatment in Youth with Schizophrenia Linmarie Sikich, M.D., (University of North Carolina, Chapel Hill)

2:55 pm – 3.20 pm

Inhibition and Stimulant Response in ADHD

3:20 pm – 3:45 pm	Steven R. Pliszka M.D., (University of Texas Health Science Center at San Antonio) MRS-Detected Brain Chemistry and Treatment Response in Pediatric OCD and Major Depressive Disorder David R. Rosenberg, M.D., (Wayne State University School of Medicine)	
3:45 pm – 3:55 pm	Break	
Drug Development – Chair: Michael E. Henry, M.D.		
3:55 pm – 4:20 pm	<i>Imaging With the Drug Companies, What Can We Expect?</i> Mark E. Schmidt, M.D. and Patricia Cole, Ph.D., M.D., (Novartis Neuroscience and Pharmaceuticals)	
4:20 pm – 4:45 pm	Development and Application of Amyloid Imaging Agents for PET C.A. Mathis, Ph.D., (University of Pittsburgh)	

The Use of ¹⁹-F MRS to Assess Pharmacokinetics in the CNS Michael E. Henry, M.D.

Thursday, May 29, 2003

PANEL 8

4:15 PM - 5:45 PM

4:45 pm – 5:10 pm

5:10 pm - 5:30 pm

New Treatment Developments for Somatoform Disorders

Chair: Javier I. Escobar, M.D., (Robert Wood Johnson Medical School)

General Discussion

4:15 pm – 4:30 pm	Cognitive-Behavioral Therapy in the Treatment of Full Somatization Disorders Lesley Allen, Ph.D., (Robert Wood Johnson Medical School)
4:30 pm – 4:45 pm	A Randomized, Controlled Intervention Trial of Cognitive- Behavior Therapy for Hypochonriasis Arthur J. Barsky, M.D., (Harvard University)
5:00 pm – 5:15 pm	CBT in the Treatment of Gulf War and Other "Functional" Syndromes Charles Engel, M.D., MPH, Uniformed Services University of the Health Sciences
5:15 pm – 5:30 pm	CBT in the Treatment of Somatization in Primary Care Javier I. Escobar, M.D
5:30 pm – 5:45 pm	General Discussion

UPDATES-II

10:45 AM - 12:15 PM

UPDATE 5

Novel Medication Delivery Systems

Herbert W. Harris, M.D., Ph.D., (Vela Pharmaceuticals)

UPDATE 6

Relapse Detection and Prevention in Anxiety Disorders

Matig Mavissakalian, M.D., (Case Western Reserve University)

UPDATE 7

Increasing Psychotropic Drug Response Predictability in African Americans and other Minorities

DiAnne Bradford, Ph.D., (Morehouse School of Medicine)

Thursday, May 29, 2003

TREATMENT DEVELOPMENT SESSION 6

9:00 AM - 11:00 AM

Cognition Across Diagnostic Entities: Shared and Unique Aspects of Cognitive Impairment Across Depression, Bipolar Disorder, Alzheimer's Disease, Schizophrenia, and NeuroAIDS

Chair: Michael Green, Ph.D., UCLA

9:00 am – 9:25 am	Cognitive Impairment in Affective Disorders Wilfred G. van Gorp, Ph.D., (Columbia University)
9:25 am – 9:50 am	Cognition and NeuroAIDS Robert K. Heaton, Ph.D., (University of California, San Diego)
9:50 am – 10:15 am	Cognitive Deficits of Alzheimer's Disease Alfred W. Kaszniak, Ph.D., University of Arizona
10:15 am – 10:35 am	Cognitive Impairments in Schizophrenia Ruben C. Gur, Ph.D., University of Pennsylvania
10:35 am – 11:00 am	Discussant: Keith Nuechterlein, Ph.D., UCLA

TREATMENT DEVELOPMENT SESSION 7

11:00 AM - 12:30 PM

Novel Target-Driven Strategies for the Treatment of Mood and Anxiety Disorders

Chair: Husseini K. Manji, M.D., (National Institute of Mental Health)

11:00 am – 11:15 am	MGluR2/3 Receptors: A Neuroanatomically Selective Target with Relevance for Pathological Stress and Anxiety Gary D. Tollefson, M.D., Ph.D., (Eli Lilly and Company)
11:15 am – 11:30 am	Ampakines Mo Shahid, M.D., (Organon)
11:30 am – 11:45 am	NPY Signaling Markus Helig, M.D., (Karolinska Institute)
11:45 am – 12:00 am	The Role of Extracellular Signal-Regulated Kinase (ERK) Pathway in Mood-Modulation Guang Chen, M.D., Ph.D., (National Institute of Mental Health)
12:00 am – 12:30 pm	General Discussion

Thursday, May 29, 2003

TREATMENT DEVELOPMENT SESSION 8

2:30 PM - 4:30 PM

Thinking Outside the Box: Future Directions in the Treatment of ADHD, Mood, and Anxiety Disorders in Children

Chair: Ellen Leibenluft, M.D., National Institute of Mental Health Intramural Research Program

2:30 pm – 2:55 pm	Use of Psychotropic Drugs in Children: A Pre-Clinical Perspective Susan L. Andersen, Ph.D., (McLean Hospital)
2:55 pm – 3:20 pm	Breakthroughs in Pharmacological and Psychological Treatments for ADHD James Swanson, Ph.D., (University of California, Irvine)
3:20 pm – 3:45pm	New Directions in the Psychopharmacology of Pediatric Anxiety Daniel S. Pine, M.D., (National Institute of Mental Health)
3:45 pm – 4:10 pm	Future Directions in the Treatment of Pediatric Bipolar Disorder Ellen Leibenluft, M.D., (National Institute of Mental Health)
4:10 pm – 4:30 pm	General Discussion

12:30 pm – 2:30 pm **Poster Session II**

Friday, May 30, 2003

FDA Symposium

9:00 AM - 12:00 Noon

Chairs: Russell Katz, M.D. and Thomas Laughren, M.D.

Food and Drug Administration

9:00 a.m. – 9:30 a.m. Surrogate Markers: Regulatory and Scientific Issues

Russell Katz, M.D.

9:30 a.m. – 10:00 a.m. Regulatory View of Cognitive Deficits in Schizophrenia as

a Target for Drug Development

Thomas Laughren, M.D.

10:00 a.m. - 10:30 a.m. An Association Between Atypical Antipsychotic Drug Use

and Cerebrovascular Adverse Events in Patients with

Dementia

Tarek Hammad, M.D., Ph.D.

10:30 a.m. - 11:00 a.m. Lumping or Splitting in Drug Claims: Mood and Physical

Symptoms of Premenstrual Dysphoric Disorder (Case in

Point)

Karen Brugge, M.D.

11:00 a.m. – 11:30 a.m. Blood (Sweat and Tears): The Role of Concentration Data

in Regulatory Review Cara Alfaro, Pharm.D.

11:30 a.m. – 12:00 p.m. **General Discussion**

Adjourn at noon

